REMARKS

Claims 21 and 23-29 are pending.

Summary of Examiner Interview

Applicants gratefully acknowledge the Examiner's time and comments during an interview on May 3, 2007. We discussed the outstanding rejections and the evidence already of record.

Rejection Under 35 U.S.C. §101 and § 112, first paragraph

Claims 21 and 23-29 remain rejected under 35 U.S.C. § 101 and § 112, first paragraph as allegedly lacking a credible, specific, or substantial asserted utility or a well established utility for reasons of record. Briefly, the Examiner continues to assert that the disclosed utilities are neither specific nor substantial because it is not clear what specific role or function FDF03 is correlated with or which specific hematopoietic cells FDF03 regulates or develops. According to the Examiner, the specification does not disclose definitive differential expression of FDF03. Applicants traverse this rejection for reasons of record as well as those discussed below.

Applicants again submit that there is no legal requirement for a certain level of specificity regarding the expression, role or function of a protein that must be achieved to satisfy the utility requirement. The utility must *merely* capable of providing some identifiable benefit according to the perspective of one of ordinary skill in the art. An applicant is not required to provide evidence sufficient to establish that an asserted utility is true "beyond a reasonable doubt" or "as a matter of statistical certainty." M.P.E.P. § 2107.02 (VII). An applicant is only required to provide evidence if, when considered as a whole, leads the skilled artisan to conclude that the asserted utility is more likely than not true. M.P.E.P. § 2107.03 (II). Furthermore, for inventions with pharmaceutical or therapeutic utilities, a reasonable correlation between the evidence and the asserted utility is sufficient. Any of the utilities disclosed for FDF03 satisfies this standard.

As evidence that a person of ordinary skill in the art would conclude that the specification provides a specific and substantial utility, we offer the declaration of Dr. Lewis Lanier. Dr. Lanier

is a scientist in the field of immunology and has considerable experience assessing the usefulness of new molecules within discrete populations. According to Dr. Lanier, there are at least two utilities that are immediate, well-defined, and real world uses of FDF03. First, Dr. Lanier opines that the FDF03 protein is immediately useful as a marker for monocytes and cells of the myelomonocytic lineage. *See* Declaration at ¶4. Despite the examiner's assertions that additional, more definitive data is required, Dr. Lanier (a person of ordinary skill in the art) believes that the specification provides sufficient evidence to persuade him that the FDF03 protein is a suitable marker for the discrete population of myelomonocytic cells as described in the specification. Second, Dr. Lanier believes that the specification describes an immediate, well-defined, real world use for FDF03 as a regulator of antigen presentation in cells of the myelomonocytic lineage (a use that is subsequently confirmed in later published documents). *See* Declaration at ¶5. As noted by Dr. Lanier, the mere fact that FDF03 plays a role in antigen presentation provides a specific and meaningful use regardless of the precise role played by FDF03.

In sum, Applicants submit that the specification provides more than one specific, substantial, and credible use for FDF03 that fulfills the utility standard. The exacting, precise standard used by the Examiner is without legal basis and demands considerably more than necessary for the person of ordinary skill in the art to appreciate the immediate, well-defined, and real world uses of FDF03 disclosed in the instant specification.

As the specification provides adequate utility for the reasons discussed above, Applicants submit that the specification also provides sufficient written description on how to use the claimed FDF03 polypeptide.

For at least these reasons as well as those already of record, Applicants respectfully submit that the rejection under 35 U.S.C. §§ 101 and 112 are overcome and should be withdrawn.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 140942001311. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: October 9, 2007

Respectfully submitted,

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